

SEP 16 2003

1/2
Special 510(k)
Contour SE™ Microspheres – Sub 500 Sizes
August 14, 2003

510(k) Summary K032542

**General
Provisions**

Trade Name: Contour SE™ Microspheres

Classification Name: Artificial Embolization Device

**Device
Description/
Indications for
Use**

The Contour SE™ Microspheres are spherical embolic particles and are available in a variety of particle sizes and are indicated for use for the embolization of hypervascular tumors and arteriovenous malformations. These particles are provided in a sterilized glass vial.

**Data Summary
Prepared**

September 15, 2003

**Contact Name/
Number**

Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation
10 Glens Falls Technical Park
Glens Falls, NY 12801

**Name of
Predicate
Devices**

Contour® Emboli PVA
Embosphere Microspheres
EmboGold Microspheres

Classification

Class III, 21 CFR 882.5950
Submitted Per 21 CFR 807

**Performance
Standards**

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

**Intended Use
and Device
Description**

Contour SE™ Microspheres are indicated for use for the embolization of hypervascular tumors and arteriovenous malformations.

Biocompatibility The Contour SE™ Microspheres have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.

Summary of Substantial Equivalence The Contour SE™ Microspheres have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2003

Ms. Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation
10 Glens Falls Technical Park
Dix Avenue
Glens Falls, New York 12885-3864

Re: K032542
Trade/Device Name: Contour SETTM Microspheres
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: August 14, 2003
Received: August 18, 2003

Dear: Ms. Greenizen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Jodi Lynn Greenizen

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

K 032542

510(k)
Number
(if known)

-Unknown

Device Name:

Contour SETTM Microspheres

Indications
for Use

Contour SETTM Microspheres are indicated for use for the embolization of hypervascular tumors and arteriovenous malformations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 032542